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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,780	11/30/2001	Roman Sakowicz	CYTOP083	9903

20350 7590 11/04/2004

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/006,780	SAKOWICZ ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached note*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *11-15*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *8-10*.

   Claim(s) withdrawn from consideration: *17 and 18*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *ATTACHED NOTE, and Form-892*

LYNETTE R. F SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

1. Applicant's after final amendment filed on 9/1/04 is acknowledged and entered.

2. Applicant states that the sole rejection that is outstanding is the rejection of claims 8-10 under 35 U.S.C. 112, first paragraph and Applicants respectfully disagree with the Office's conclusion for at least two general reasons: (i) the Office is applying an incorrect enablement standard, and (ii) the rationale presented in the Office Action is inconsistent with statements regarding enablement issues in the "Synopsis of Application of Written Description Guidelines" (Guidelines) promulgated by the Office.
With respect to the appropriate standard for enablement, the Office maintains the view that protein chemistry is highly unpredictable and cites several articles to support its conclusion that it would require undue experimentation to identify active variants of SEQ ID.NOs:2, 4, 6, 8 and 10 because the effect of protein alterations "cannot be predicted a priori and must be determined empirically on a case-by-case basis. It thus appears that the Office is taking the position that variants cannot be claimed unless the specification provides sufficient guidance such that one of ordinary skill in the art can predict a priori what amino acid alterations can be made to SEQ ID N0: 2, 4, 6, 8, and 10 without altering the function of the native protein. Applicant more specifically states that the In re Wands decision indicates that experimentation is not deemed to be undue if EITHER of two requirements are satisfied: (1) the experimentation is routine, OR (2) the specification provides reasonable guidance in the direction the experimentation should proceed. Although only one of these criteria need be satisfied, it is submitted that the specification satisfies both.

The examiner disagrees with the applicant because the specification fails to provide guidance how to make and use an isolated protein, wherein (a) the protein comprises a sequence that has greater than 90% amino acid sequence identity to SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID N0: 6, SEQ ID N0: 8, or SEQ ID NO: 10 as measured using a sequence comparison algorithm, and (b) has microtubule stimulated ATpase activity because an isolated polypeptide comprises (open language) a sequence that has greater than 90%identity to SEQ ID NO: 2, 4, 6, 8 or 10 plus unlimited and unknown amino acids would result in an unknown variants without any structure and other identifying characteristics such as function. Thus, variants/fragments as claimed are broader than SEQ.ID.NO: 2, 4,

Applicant states that the specification teaches that the claimed PfKinI-1 proteins are members of the Kinesin I subfamily that is part of the larger kinesin family of proteins (see, e.g., paragraph (0004)), that the PfKinI-1 proteins are homologous with HsKin I-3 (see, e.g., paragraph (0065)), and that some Pfkin1-I proteins include a motor domain, Which is a common feature of the kinesin family of proteins (see, e.g., paragraph (0068)). Those of ordinary skill in the art would thus know that one logical approach for obtaining active variants of SEQ ID N0s: 2, 4, 6, 8 and 10 that have microtubule-stimulated activity would involve first identifying conserved and non-conserved regions between the listed protein sequences and related members of the Kinesin I family. This could be readily done using sequence comparison algorithms such as those listed in the specification (see, e.g., paragraphs (00292- (00311). Skilled practitioners would further recognize that likely candidates for alteration that would still yield an active protein would be those amino acids in non-conserved regions, as such regions by definition appear to tolerate differences in sequence. Another useful strategy would be to make mutations outside the motor domain because of its role in the activity of the protein. It is thus submitted that the guidance in the specification coupled with the general knowledge in the art would have enabled one of ordinary skill to identify appropriate residues for modification.

The examiner disagrees with the applicant because The assertion that the disclosed isolated protein have biological activities similar to known Human kinesin family is not credible in the absence of supporting evidence, because the relevant literature reports numerous examples of polypeptide families wherein individual members have distinct, and even opposite, biological activities. For example, Hitomi et al (US Patent 6,313,267) states that calcium binding proteins with EF-hands are diverse in function (see column 1, lines 18-37). In addition, Tischer et al. (U.S. Patent 5,194,596) establishes that VEGF (a member of the PDGF, or platelet-derived growth factor, family) is mitogenic for vascular endothelial cells but not for vascular smooth muscle cells, which is opposite to the mitogenic activity pf naturally occurring PDGF which is mitogenic for vascular smooth muscle cells but not for vascular endothelial cells (column 2, line 46 to column 3, line 2). Therefore, asserting a parasite protein to have biological properties with a human protein are not proper and credible in spite of knowing and using sequence comparison algorithms as recited in the specification because generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick et al. (2000, Trends in Biotech. 18:34-39) state that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36).

Finally applicant states that the current rejection is an enablement rather than written description rejection, but the Guidelines nonetheless are pertinent to the current rejection. As noted in the last response, Example 14 in the Guidelines focuses on a claim example that is similar to the pending claims.

As stated previously, again the examiner disagrees with the applicant because the written description requirement is the claim(s) contains subject matter which is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, where as the requirement for enablement is the specification should be enabled to make and use the invention. As discussed above the specification is not enabled for this broadly claimed invention. Therefore, the rejection is maintained.

3. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272□0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi□week.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.
Padma Baskar Ph.D.